

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

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In Re: PHARMACEUTICAL INDUSTRY	:	
AVERAGE WHOLESALE PRICE	:	
LITIGATION	:	MDL No. 1456
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THIS DOCUMENT RELATES TO:	:	Master File No. 01-CV-12257-PBS
	:	
State of Montana v. Abbott Laboratories, Inc.	:	Judge Patti B. Saris
et al., D Mont. Cause No. CV-02-09-H-DWM	:	
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**DEY, INC.'S ANSWER TO THE STATE OF
MONTANA'S SECOND AMENDED COMPLAINT**

Defendant Dey, Inc. ("Dey"), by its attorneys, Kelley Drye & Warren LLP, for its Answer to the State of Montana's Second Amended Complaint (the "Complaint"), states:

1. Dey denies the allegations in Paragraph 1 of the Complaint, except admits that Plaintiff purports to bring this action as alleged in Paragraph 1 of the Complaint.
2. Insofar as the allegations in the first sentence of Paragraph 2 of the Complaint are directed at Dey, Dey admits those allegations, except denies that Dey marketed to purchasers in the State of Montana. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the remainder of Paragraph 2 and, therefore, denies those allegations.
3. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and, therefore, denies those allegations.

4. To the extent that the allegations in Paragraph 4 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 4 of the Complaint.

5. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and, therefore, denies those allegations, except admits that pharmaceutical industry pricing publications periodically report AWP's for prescription drugs sold in the United States.

6. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of the Complaint and, therefore, denies those allegations.

7. Dey denies the allegations in Paragraph 7 of the Complaint.

8. Dey denies the allegations in Paragraph 8 of the Complaint.

9. Dey denies the allegations in Paragraph 9 of the Complaint.

10. Dey denies the allegations in Paragraph 10 of the Complaint.

11. Dey denies the allegations in Paragraph 11 of the Complaint and respectfully refers the Court to the statutes, regulations, and/or rules, as well as the referenced agreements, as the best evidence of their contents.

12. Dey denies the allegations in Paragraph 12 of the Complaint.

13. Dey denies the allegations in Paragraph 13 of the Complaint.

14. Dey denies the allegations in Paragraph 14 of the Complaint.

15. Dey denies the allegations in Paragraph 15 of the Complaint.

16. Dey denies the allegations in Paragraph 16 of the Complaint.

17. Dey denies the allegations in Paragraph 17 of the Complaint.

18. Dey denies the allegations in Paragraph 18 of the Complaint, except admits that the State purports to bring this action to recover alleged damages and/or for restitution.

19. Dey denies the allegations in Paragraph 19 of the Complaint.

20. Dey denies the allegations in Paragraph 20 of the Complaint, except denies having knowledge or information sufficient to form a belief as to the truth of the allegations regarding the requirement that members of the “general public” make co-payments.

21. Dey denies the allegations in Paragraph 21, of the Complaint, except admits that the State purports to bring this action as alleged.

22-23. Dey denies the allegations in Paragraphs 22-23 of the Complaint, except admits that the State purports to bring this action for the reasons alleged.

24. Dey denies the allegations in Paragraph 24 of the Complaint, except admits that the State purports to bring this action as alleged.

25. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 of the Complaint and, therefore, denies those allegations.

26. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 of the Complaint and, therefore, denies those allegations.

27. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of the Complaint and, therefore, denies those allegations.

28. Dey denies the allegations in the first sentence of Paragraph 28 of the Complaint and respectfully refers the Claim to the applicable statutes, regulations, and/or rules as the best evidence of those services the Montana Medicaid Program is required to provide. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in

the second and third sentences of Paragraph 28 of the Complaint and, therefore, denies those allegations.

29. To the extent that the allegations in Paragraph 29 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore denies those allegations. Dey denies the remaining allegations in Paragraph 29 of the Complaint.

30. To the extent that the allegations in Paragraph 30 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey otherwise denies the allegations in Paragraph 30 of the Complaint, except admits that it transacted business in the State of Montana.

31-66. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 31 through 66 of the Complaint insofar as they are directed to other defendants. To the extent that the allegations in Paragraphs 31 through 66 of the Complaint are deemed to include allegations against Dey, they are denied.

67. Dey admits that it is a Delaware corporation with its principal place of business located at 2751 Napa Valley Corporate Drive, Napa, California and that Merck KGaA is a corporation organized and existing pursuant to the laws of the Federal Republic of Germany and is the ultimate parent of Dey. Dey denies the remaining allegations in Paragraph 67 of the Complaint.

68. Dey admits that it is a specialty pharmaceutical company that develops, manufactures, and markets certain generic drugs used in the treatment of, among other things,

respiratory diseases and allergies. Dey also admits that it had net sales in 1998 of \$266 million. Dey denies the remaining allegations in Paragraph 68 of the Complaint.

69. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 of the Complaint, except admits that it manufactures drugs available to beneficiaries of the Montana Medicaid Program.

70-111. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 70 through 111 of the Complaint insofar as they are directed to other defendants. To the extent that the allegations in Paragraphs 70 through 111 of the Complaint are deemed to include allegations against Dey, they are denied.

112-121. Dey denies the allegations in Paragraphs 112 through 121 of the Complaint and respectfully refers the Court to the publications referenced in those paragraphs as the best evidence of their contents.

122. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 122 of the Complaint and, therefore, denies those allegations.

123. Dey denies the allegations in Paragraph 123 of the Complaint.

124-141. The allegations set forth in Paragraphs 124 through 141 contain Plaintiff's self-serving conclusions and generalizations regarding the Prescription Drug Market without specific detailed factual allegations averred against Dey. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied. Moreover, the allegations set forth in Paragraphs 124 through 141 contain alleged findings, opinions, statements or conclusions from the "Chartbook." Dey avers that the Chartbook is the best evidence of its content. Dey denies that Plaintiff has accurately characterized any alleged

finding, opinion, statement or conclusion contained therein, or that such are applicable to Dey. Dey is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

142. Dey admits the allegations in Paragraph 142 of the Complaint.

143. Dey admits the allegations in Paragraph 143 of the Complaint.

144. Dey denies the allegations in Paragraph 144 of the Complaint and respectfully refers the Court to the relevant portions of the Social Security Act as the best evidence of its contents.

145. Dey denies the allegations in Paragraph 145 of the Complaint and respectfully refers the Court to the applicable statutes, rules, and/or regulations, as well as the referenced publication, as the best evidence of the drugs covered by Part B of the Medicare Program.

146. Dey denies the allegations in Paragraph 146 of the Complaint and respectfully refers the Court to 42 C.F.R. § 405.517 as the best evidence of its contents.

147. Dey denies the allegations in Paragraph 147 of the Complaint and respectfully refers the court to the applicable statutes, regulations, and/or rules as the best evidence of the means by which estimated acquisition cost for a drug may be determined.

148. Dey denies the allegations in Paragraph 148 of the Complaint and respectfully refers the Court to 42 C.F.R. § 405.517 as the best evidence of its contents.

149. Dey denies the allegations in Paragraph 149 of the Complaint and respectfully refers the Court to Program Memorandum AB-99-63, cited in Paragraph 149 of the Complaint, as the best evidence of its contents.

150. Dey denies the allegations in Paragraph 150 of the Complaint, and refers the Court to the Program Memorandum AB-99-63, cited in Paragraph 150 of the Complaint, as the best evidence of its contents.

151. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 151 of the Complaint and, therefore, denies those allegations, except admits that there are no government regulations describing how AWP's are calculated, nor any other statutory or regulatory definitions or descriptions of AWP's, and that it reports certain pricing information for its drugs to pharmaceutical industry pricing publications.

152-153. Dey admits the allegations in Paragraphs 152 and 153 of the Complaint.

154. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 154 of the Complaint and, therefore, denies those allegations.

155. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 155 of the Complaint and, therefore, denies those allegations.

156. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 156 of the Complaint and, therefore, denies those allegations.

157. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 157 of the Complaint and, therefore, denies those allegations.

158. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 158 of the Complaint and, therefore, denies those allegations.

159. Dey denies the allegations in Paragraph 159 of the Complaint and respectfully refers the Court to 42 C.F.R. § 440.121 as the best evidence of its contents.

160. Dey denies the allegations in Paragraph 160 of the Complaint, and refers the Court to the relevant Montana statutes, regulations and/or rules as the best evidence of the prescription drug coverage provided by the Montana Medicaid Program.

161. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 161 of the Complaint and, therefore, denies those allegations.

162. Dey denies the allegations in Paragraph 162 of the Complaint and respectfully refers the Court to Mont. Admin. R. 37.86.1105, Mont Admin. R. 37.86.1101, 42 C.F.R. § 447.331-32, and the referenced Montana publication as the best evidence of the formulas applicable to Medicaid reimbursement in Montana.

163. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 163 of the Complaint, and therefore, denies those allegations.

164. Dey denies the allegations in Paragraph 164 of the Complaint.

165. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 165 of the Complaint and, therefore, denies those allegations, except admits patients receive drugs from physicians, pharmacies, and other

healthcare providers and that, in certain contexts, AWP forms the basis for the reimbursement paid to providers for drugs.

166. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 165 of the Complaint, except denies that it was “aware” of the actions and knowledge of unspecified “participants” and admits that, in certain contexts, AWP forms the basis for the reimbursement paid to providers for drugs.

167. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 167 of the Complaint, except Dey admits that pharmaceutical industry pricing publications periodically report AWP for prescription drugs sold in the United States.

168. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first through fourth sentences of Paragraph 168 of the Complaint and respectfully refers the Court to the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 168 as the best evidence of their contents. Dey denies the remaining allegations in Paragraph 168 of the Complaint and respectfully refers the Court to the complaint cited in Paragraph 168 as the best evidence of its contents.

169. Dey denies the allegations in Paragraph 169 of the Complaint.

170-171. Dey denies the allegations in Paragraphs 170 and 171 of the Complaint and respectfully refers the Court to the referenced April 2003 OIG report as the best evidence of its contents.

172. Dey denies the allegations in Paragraph 172 of the Complaint.

173. Dey denies the allegations in Paragraph 173 of the Complaint.

174. Dey denies the allegations in Paragraph 174 of the Complaint.

175. Dey denies the allegations in Paragraph 175 of the Complaint.

176. To the extent that the allegations in Paragraph 176 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, except admits that it provided AWP's to certain pharmaceutical compendia.

177-184. To the extent that the allegations in Paragraphs 177 through 184 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, but otherwise denies the allegations in Paragraph 177 through 184 of the Complaint.

185. Dey denies the allegations in Paragraph 185 of the Complaint.

186. Dey denies the allegations in Paragraph 186 of the Complaint.

187. Dey denies the allegations in Paragraph 187 of the Complaint and respectfully refers the Court to 42 C.F.R. § 405.517 as the best evidence of its contents.

188. Dey denies the allegations in Paragraph 188 of the Complaint and respectfully refers the Court to Mont. Admin. R. 37.86.1101 and 42 C.F.R. § 447.332 as the best evidence of their contents.

189. To the extent that the allegations in Paragraph 189 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, but otherwise denies the allegations in Paragraph 189 of the Complaint.

190. Dey denies the allegations in Paragraph 190 of the Complaint and respectfully refers the Court to the applicable federal and Montana statutes, regulations, and/or rules as the best evidence of the formulas by which reimbursement for generic drugs is calculated.

191. Dey denies the allegations in Paragraph 191 of the Complaint.

192. Dey denies the allegations in Paragraph 192 of the Complaint.

193-195. To the extent that the allegations in Paragraphs 193 through 195 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations but otherwise denies the allegations in Paragraphs 193 through 195 of the Complaint.

196. To the extent that the allegations in Paragraph 196 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 196 of the Complaint.

197-200. Dey denies the allegations in Paragraphs 197 through 200 of the Complaint and respectfully refers the Court to the complaint cited in Paragraphs 197 through 200 as the best evidence of its contents.

201-209. To the extent that the allegations in Paragraphs 201 through 209 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, but otherwise denies the allegations in Paragraph 201 through 209 of the Complaint.

210. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 210 of the Complaint, except admits that it is aware that certain investigations are occurring.

211-212. Dey denies the allegations in Paragraphs 211 and 212 of the Complaint and respectfully refers the Court to the referenced letter as the best evidence of its contents.

213. To the extent the allegations in Paragraph 213 refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations. Dey denies the remaining allegations in Paragraph 213, except admits it is aware that certain investigators are ongoing.

214-215. To the extent that the allegations in Paragraphs 214 through 215 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, but otherwise denies the allegations in Paragraph 214 through 215 of the Complaint.

216-385. The allegations in Paragraphs 216 through 385 of the Complaint are directed to other defendants and require no response from Dey. To the extent that the allegations in Paragraphs 216 through 385 of the Complaint are deemed to require a response, they are denied.

386. Dey denies the allegations in Paragraph 386 of the Complaint.

387. Dey denies the allegations in Paragraph 387 of the Complaint except admits that Appendix A purports to set forth the specific drugs “for which relief is currently sought.”

388. Dey denies the allegations in Paragraph 388 of the Complaint, except admits that it reported certain pricing information for its drugs to pharmaceutical industry pricing publications and that it reported suggested AWP prices, and further admits that it prepared the document Bates stamped DL-CA 00120, cited in Paragraph 388 of the Complaint, but Dey states that this document is the best evidence of its contents and denies that the conclusions that the State draws from this document are accurate. Dey denies that it prepared the document Bates stamped DL-CA 00080, cited in Paragraph 388 of the Complaint, except Dey admits that the referenced, handwritten notations on DL-CA 00080 were made by a Dey employee.

389. Dey denies the allegations in Paragraph 389 of the Complaint, and refers the Court to the complaint cited in Paragraph 389 as the best evidence of its contents.

390. Dey denies the allegations in Paragraph 390 of the Complaint.

391. Dey denies the allegations in Paragraph 391 of the Complaint.

392. Dey denies the allegations in Paragraph 392 of the Complaint, except admits that it prepared the documents cited in Paragraph 392 of the Complaint (DL-TX-0090852 and DL-TX-0090854) but states that these documents are the best evidence of their contents and denies that the conclusions the State draws from these documents, if any, are accurate.

393-394. Dey denies the allegations in Paragraphs 393 and 394 of the Complaint, except admits that it prepared the documents cited in Paragraphs 393 and 394 of the Complaint (DL-TX-0014029 and DL-TX-0014439) but states that these documents are the best evidence of their contents and denies that the conclusions the State draws from these documents are accurate.

395-397. To the extent that the allegations in Paragraphs 395 through 397 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth

of those allegations and, therefore, denies those allegations. Dey states that the reports published by the OIG (OEI-03-01-00410, March 2002), cited and referred to in Paragraphs 395 and 396 of the Complaint, and the report published by the GAO (see “MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers’ Cost”), cited in Paragraph 397 of the Complaint, are the best evidence of their contents, but Dey denies that the State has accurately characterized any alleged finding, opinion, statement or conclusion contained in these documents. Dey admits that albuterol sulfate is a multiple-source drug manufactured and/or marketed by Dey. Dey denies the remaining allegations in Paragraphs 395 through 397 of the Complaint.

398. To the extent that the allegations in Paragraph 398 of the Complaint refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies that the document cited as the source for “Table 1” in Paragraph 398 of the Complaint is a document prepared by Dey and further denies that this document reflects any conduct by or knowledge of Dey. Dey further denies that “Table 1” in Paragraph 398 of the Complaint accurately reflects the contents of the cited document (DL-TX 0011179), and otherwise denies the allegations in Paragraph 398.

399. To the extent that the allegations in Paragraph 399 of the Complaint refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 399 of the Complaint, except admits that the AWP for the referenced drug did not change during the referenced period.

400. Paragraph 400 states legal conclusions as to which no response is required. To the extent a response is required, Dey denies the allegations in Paragraph 400 of the Complaint.

401. Dey denies the allegations in Paragraph 401 of the Complaint and respectfully refers the Court to the 1999 edition of the *Red Book* cited in Paragraph 401 as the best evidence of its contents.

402-403. To the extent the allegations in Paragraphs 402 and 403 of the Complaint refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey admits that it prepared the document cited in Paragraph 403 of the Complaint (DL-TX-0004775), but Dey states that this document is the best evidence of its contents and denies that the conclusions the State draws from this document are accurate. Dey denies the remaining allegations in Paragraphs 402 and 403.

404. Dey denies the allegations in Paragraph 404 of the Complaint, except admits that the governmental agencies listed in Paragraph 404 of the Complaint have conducted investigations concerning pricing in the pharmaceutical industry and that Dey, among others, has participated in certain of such investigations.

405. Dey denies the allegations in Paragraph 405 of the Complaint, and refers the Court to the editions of the Red Book and the September 25, 2000, letter from Representative Bliley to Nancy-Ann DeParle as the best evidence of their contents.

406. Dey denies the allegations in Paragraph 406, except Dey admits that it paid the State of Texas \$18,500,000 in settlement of an action brought by Texas.

407-408. Dey denies the allegations in Paragraphs 407 and 408 of the Complaint, except admits that the Attorneys General of Texas, West Virginia and Connecticut have

commenced actions against Dey, and refers the Court to the pleadings in those actions as the best evidence of their contents.

409. To the extent that the allegations in Paragraph 409 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey states that the report published by the DHHS, cited in Paragraph 409 of the Complaint, is the best evidence of its contents, but Dey denies that the State has accurately characterized any alleged finding, opinion, statement or conclusion contained in such report. Dey admits that it sells its medicines at prices below AWP, which is a non-discounted list price. Dey denies the remaining allegations in Paragraph 409.

15. To the extent that the allegations in the Paragraph erroneously denominated “15” of the Complaint refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey admits that it prepared the document cited in the Paragraph erroneously denominated “15” of the Complaint (DL-TX-0024844), but Dey states that this document is the best evidence of its contents and denies that the conclusions the State draws from this document are accurate. Dey denies the remaining allegations in the Paragraph erroneously denominated “15” of the Complaint.

410-602. The allegations in Paragraphs 410 through 602 of the Complaint are directed to other defendants and require no response from Dey. To the extent that the allegations in Paragraphs 410 through 602 of the Complaint are deemed to require a response, they are denied.

603-634. The allegations in Paragraphs 603 through 634 of the Complaint are directed to other defendants and require no response from Dey as the Court dismissed the “Best Price” claims with respect to Dey. *See In re Pharmaceutical Industry Average Wholesale Price Litig.*, MDL No. 1456, Civil Action No. 01-12257-PBS, slip op. at 34 (D. Mass. June 10, 2004) (hereinafter, “*AWP Litig.*”). To the extent that the allegations in Paragraphs 603 through 634 of the Complaint are deemed to require a response, they are denied.

635. Dey denies the allegations in Paragraph 635 of the Complaint.

636. To the extent that the allegations in Paragraph 636 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey respectfully refers the Court to the 2003 CMS document, cited in Paragraph 636 of the Complaint, as the best evidence of its contents. Dey denies the remaining allegations in Paragraph 636, except admits that it sells its drugs in a competitive market and, as such, takes steps to keep certain information relating to its drugs confidential.

637-640. To the extent that the allegations in Paragraphs 637 through 640 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 637 through 640 of the Complaint.

641-643. Dey denies the allegations in Paragraphs 641 through 643 of the Complaint.

644. Dey denies the allegations in Paragraph 644 of the Complaint.

645. Dey denies the allegations in Paragraph 645 of the Complaint, except admits that certain recipients of drugs under the Medicare Part B program pay a 20 percent co-payment.

646. To the extent that the allegations in Paragraph 646 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies these allegations. Dey denies the remaining allegations in Paragraph 646 of the Complaint.

647. To the extent that the allegations in Paragraph 647 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies these allegations. Dey denies the remaining allegations in Paragraph 647 of the Complaint.

648. Dey denies the allegations in Paragraph 648 of the Complaint.

649. To the extent that the allegations in Paragraph 649 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies these allegations. Dey denies the remaining allegations in Paragraph 649 of the Complaint.

650. Dey denies the allegations in Paragraph 650 of the Complaint.

651. The allegations in Paragraph 651 of the Complaint are directed to other defendants and require no response from Dey as the Court dismissed the “Best Price” claims

with respect to Dey. *See AWP Litig.* at 34. To the extent that the allegations in Paragraph 651 of the Complaint are deemed to require a response, they are denied.

652. Dey denies the allegations in Paragraph 652 of the Complaint.

653. To the extent that the allegations in Paragraph 653 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 653 of the Complaint.

AS AND FOR AN ANSWER TO COUNT I

654. Answering Paragraph 654 of the Complaint, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 653 of the Complaint.

655. Dey denies the allegations in Paragraph 655 of the Complaint, except admits that the State purports to bring a claim for restitution pursuant to Mont. Code Ann. §§ 30-14-1414 as alleged in Paragraph 655 of the Complaint.

656-660. Dey denies the allegations in Paragraphs 656 through 660 of the Complaint.

WHEREFORE paragraph following Paragraph 660. Dey denies the State is entitled to a judgment or any other relief requested in their “WHEREFORE” paragraph (and sub-paragraphs) following Paragraph 660 of the Complaint.

AS AND FOR AN ANSWER TO COUNT II

661. Answering Paragraph 661 of the Complaint, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 660 of the Complaint.

662. Dey denies the allegations in Paragraph 662 of the Complaint, except admits that the State purports to bring claims for restitution, civil penalties and injunctive relief pursuant to Mont. Code Ann. §§ 30-14-1414 as alleged in Paragraph 662 of the Complaint.

663-667. Dey denies the allegations in Paragraphs 663 through 667 of the Complaint.

WHEREFORE paragraph following Paragraph 667. Dey denies the State is entitled to a judgment or any other relief requested in their “WHEREFORE” paragraph (and sub-paragraphs) following Paragraph 667 of the Complaint.

AS AND FOR AN ANSWER TO COUNT III

668. Answering Paragraph 668 of the Complaint, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 667 of the Complaint.

669-679. The allegations in Paragraphs 669 through 679 of the Complaint are directed to other defendants and require no response from Dey as the Court dismissed this claim with respect to Dey. *See AWP Litig.* at 34. To the extent that the allegations in Paragraphs 669 through 679 of the Complaint are deemed to require a response, they are denied.

WHEREFORE paragraph following Paragraph 679. Dey denies the State is entitled to a judgment or any other relief requested in their “WHEREFORE” paragraph (and sub-paragraphs) following Paragraph 679 of the Complaint.

AS AND FOR AN ANSWER TO COUNT IV

680. Answering Paragraph 680 of the Complaint, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 679 of the Complaint.

681-691. The allegations in Paragraphs 681 through 691 of the Complaint are directed to other defendants and require no response from Dey as the Court dismissed this claim.

See AWP Litig. at 22. To the extent that the allegations in Paragraphs 681 through 691 of the Complaint are deemed to require a response, they are denied.

WHEREFORE paragraph following Paragraph 691. Dey denies the State is entitled to a judgment or any other relief requested in their “WHEREFORE” paragraph (and sub-paragraphs) following Paragraph 691 of the Complaint.

692. Answering Paragraph 692 of the Complaint, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 691 of the Complaint.

693. To the extent that the allegations in Paragraph 693 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 693 of the Complaint.

WHEREFORE paragraph following Paragraph 693. Dey denies the State is entitled to a judgment or any other relief requested in their “WHEREFORE” paragraph (and sub-paragraphs) following Paragraph 693 of the Complaint.

AFFIRMATIVE AND OTHER DEFENSES

First Defense

Plaintiff fails to state a claim against Dey upon which relief may be granted.

Second Defense

Plaintiff’s claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Third Defense

Plaintiff’s claims are barred, in whole or in part, by the filed rate doctrine.

Fourth Defense

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Dey as alleged in the Complaint.

Fifth Defense

To the extent that Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Dey based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

Sixth Defense

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and Article II, Section 7 of the Constitution of the State of Montana.

Seventh Defense

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Dey in judicial, legislative or administrative proceedings of any kind or at any level of government.

Eighth Defense

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

Ninth Defense

Any and all actions taken by Dey with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

Tenth Defense

Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eleventh Defense

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

Twelfth Defense

Plaintiff's claims against Dey are barred because Dey has complied with all applicable regulations of the federal and state governments.

Thirteenth Defense

Plaintiff's claims against Dey are barred, in whole or in part, by the applicable statutes of limitations and repose.

Fourteenth Defense

Plaintiff's claims against Dey are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, and unclean hands.

Fifteenth Defense

Plaintiff's claims against Dey are barred, in whole or in part, as a result of the knowledge of the federal government and/or the knowledge of the government of the State of Montana.

Sixteenth Defense

Plaintiff's claims are barred, in whole or in part, because they violate Dey's rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as Article II, Section 17 (Due Process of Law) and Article II, Section 31 (Ex Post Facto Laws) of the

Constitution of the State of Montana, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Seventeenth Defense

Plaintiff fails to state with particularity facts to support the fraud and/or fraudulent concealment allegations against Dey contained in the Complaint.

Eighteenth Defense

Plaintiff fails to plead with particularity its multi-source drug allegations against Dey in the Complaint.

Nineteenth Defense

Plaintiff fails to state with particularity facts to support the Deceptive Trade Practices and False Claims Act claims against Dey contained in the Complaint.

Twentieth Defense

Plaintiff fails to state with particularity facts to support the Medicaid Fraud claims against Dey contained in the Complaint.

Twenty-First Defense

Plaintiff's claims against Dey for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Twenty-Second Defense

Plaintiff's claims for injunctive relief against Dey are barred by the doctrines of *in pari delicto* and/or unclean hands.

Twenty-Third Defense

Plaintiff's claims against Dey are barred, in whole or in part, due to its failure to join indispensable parties.

Twenty-Fourth Defense

Plaintiff's claims against Dey are barred, in whole or in part, because is has suffered no damages as a result of the matters alleged in the Complaint.

Twenty-Fifth Defense

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superceding conduct of third parties.

Twenty-Sixth Defense

Plaintiff's claims against Dey for damages are barred, in whole or in part, because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery by Plaintiff and the allocation of any fault, if any exists, attributable to Dey.

Twenty-Seventh Defense

Plaintiff's claims against Dey for damages are barred, in whole or in part, because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

Twenty-Eighth Defense

Dey is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

Twenty-Ninth Defense

Plaintiff's claims against Dey for damages are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received or paid for drugs manufactured, marketed and sold by Dey after the filing of Plaintiff's original Complaint.

Thirtieth Defense

Any damages recovered by the Plaintiff from Dey must be limited by the applicable statutory ceilings on recoverable damages.

Thirty-First Defense

Plaintiff fails to allege facts or a cause of action against Dey sufficient to support a claim for attorneys' fees, double damages and/or punitive damages.

Thirty-Second Defense

To the extent punitive damages are sought, Plaintiff's claims against Dey cannot be sustained because an award of punitive damages would violate the Excessive Fines Clause of the Eighth Amendment and the Due Process Clauses of the Fifth and Fourteenth Amendments of the United States Constitution, as well as Article II, Section 17 (Due Process of Law) and Article II, Section 22 (Excessive Sanctions) of the Constitution of the State of Montana.

Thirty-Third Defense

During the relevant time period, the Plaintiff did not regard AWP as anything other than a list or "sticker" price which it discounted for both branded and generic drugs when determining reimbursement rates.

Thirty-Forth Defense

Plaintiff is estopped from claiming entitlement to the sum it seeks because it has known throughout the relevant time period that the AWP's published in industry sources did not reflect actual net prices charged by Dey to wholesalers or others and, therefore, Plaintiff could not have reasonably relied on these published prices if it were seeking to reimburse on wholesaler price or some other customary price basis.

Thirty-Fifth Defense

Plaintiff's claims are barred to the extent that the claims involve drugs reimbursed without reference to AWP.

Thirty-Sixth Defense

Plaintiff was negligent, careless, committed willful misconduct or was otherwise at fault in and about the matter referred to in the Complaint, and such conduct on the part of Plaintiff caused and contributed to the injury complained of, if any actually occurred.

Thirty-Seventh Defense

Plaintiff directed, ordered, approved and/or ratified Dey's conduct, and Plaintiff is, therefore, barred from asserting any claims based thereon.

Thirty-Eight Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of mistake and mutual mistake.

Thirty-Ninth Defense

To the extent civil penalties are sought, civil penalties against Dey cannot be sustained because an award of the civil penalties sought by Plaintiff would violate the United States Constitution, Excessive Fines Clause of the Eighth Amendment, U.S. Const. amend. VIII, and the Due Process Clauses of the Fifth and Fourteenth Amendments, U.S. Const. amend. V and XIV, and the analogous provisions in the Montana State Constitution.

Fortieth Defense

Any or all causes of action in Plaintiff's Complaint are barred because of the lack of privity between Plaintiff and Dey.

Forty-First Defense

Any or all causes of action in Plaintiff's Complaint are barred because the statutes upon which Plaintiff relies are vague and ambiguous.

Forty-Second Defense

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Forty-Third Defense

Dey adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Forty-Fourth Defense

Dey hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

Forty-Fifth Defense

To the extent equitable relief is sought, such claims cannot be sustained because Plaintiff has an adequate remedy at law.

WHEREFORE, Dey respectfully requests that the Court:

1. Dismiss the State of Montana's Second Amended Complaint with prejudice and enter judgment in favor of Dey and against Plaintiff;
2. Award Dey its costs, expenses, and attorneys' fees; and
3. Grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: July 12, 2004

Respectfully submitted,

KELLEY DRYE & WARREN LLP

By: s/ Christopher C. Palermo [signature on file]

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Attorneys for Defendant Dey, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of July, 2004, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

s/ Philip D. Robben [signature on file]

Philip D. Robben

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